

I hereby certify that this correspondence is being deposited with the U.S. Postal Services as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents. Washington, D.C. 20231 on: January 7, 2003  
Name: John A. Sopp (Reg. No. 33,103)  
Signature: *[Signature]*  
Date: January 7, 2003

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Wolfgang HEIL et al.

Serial No.: 09/654,227

Examiner: M. Bahar

Filed: August 31, 2000

Group Art Unit: 1617

Title: PHARMACEUTICAL COMPOSITION FOR USE AS A CONTRACEPTIVE

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

**CITED MATERIALS**

Applicant(s) hereby disclose the information listed in the attached form PTO-1449.

- ☐ Copies of materials listed but not attached were cited in parent application Serial No. \_\_\_\_; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an International Search Report dated \_\_\_\_; receipt of the International Search Report and copies of references was confirmed by the PCT International Division of the U.S. PTO in the Notice of Acceptance mailed \_\_\_\_.

**ADDITIONAL INFORMATION**

None

**LANGUAGE**

- ☐ All listed materials are in the English language; see 37 C.F.R. § 1.98.
- ☒ Non-English language references:

- ☐ The reference(s): \_\_\_\_\_ in the English-language is (are) indicated by commercial data bases to correspond to the reference(s): \_\_\_\_\_, respectively.
- ☒ An English-language translation of the reference: C4 is provided.
- ☐ A commercial English-language abstract of reference(s) \_\_\_\_\_ is (are) provided.
- ☐ An English-language search report or an equivalent paper from a foreign patent office translated into English in pertinent part in connection with a counterpart foreign application, is provided indicating the relevance of the cited reference(s).

**FEES**

- ☒ No fee is required for this Information Disclosure Statement because it is filed with an RCE filing.:
  - ☐ This Information Disclosure Statement is being filed within three months of the filing date of a national application (other than a CPA) under § 1.53(d) or within 3 months of the date of entry of the national stage under § 1.491 in an international application;
  - ☐ This Information Disclosure Statement is being filed before the mailing of a first action on the merits;
  - ☐ This Information Disclosure Statement is being filed after a first action on the merits but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that closes prosecution in the application, and is accompanied by a certification below.
  - ☐ This Information Disclosure Statement is filed under 37 C.F.R. § 1.97(i).
- ☐ A fee is required for this Information Disclosure Statement:
  - ☐ This Information Disclosure Statement is being filed after a first action on the merits but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311 or an action that closes prosecution, and is accompanied by the fee set forth in § 1.17(p).
  - ☐ This Information Disclosure Statement is being filed after the mailing date of a final rejection or a notice of allowance under § 1.311 or an action that closes prosecution, but before the payment of the issue fee, and is accompanied by the fee set forth in § 1.17(p) and a certification below.

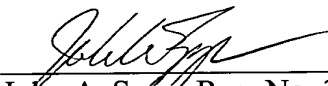
**CERTIFICATION**

- ☐ Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned, having made reasonable inquiry, no such item was known to any individual designated in 37 CFR § 1.56(c), more than three months prior to the filing of this statement.

**DEPOSIT ACCOUNT**

If a fee is due, attached is a check in the amount of \$180.00. However, the Commissioner is hereby authorized to charge fees under 37 CFR § 1.16 and § 1.17 which may be required to facilitate this filing, or credit any overpayment to Deposit Account No. 13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

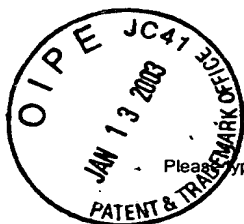
  
\_\_\_\_\_  
John A. Sopp, Reg. No. 33,103  
Attorney for Applicants

MILLEN, WHITE, ZELANO &  
BRANIGAN, P.C.  
Arlington Courthouse Plaza 1, Suite 1400  
2200 Clarendon Boulevard  
Arlington, Virginia 22201  
Telephone: (703) 243-6333  
Facsimile: (703) 243-6410

Attorney Docket No.: PLOVIN-1A

Date: January 7, 2003

K:\Plovin\1 A\Amd for RCE.doc



Please type a plus sign (+) inside this box → ☐

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

### Complete if Known

Application Number	09/654,227
Filing Date	August 31, 2000
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1617
Examiner Name	M. Bahar
Attorney Docket Number	PLOVIN-1A

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	4,621,079		Lachnit-Fixson et al.	11-04-1986	
	A2	5,569,652	A1	Beier et al.	10-29-1996	

### FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sub>6</sub>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	B1	WO	97/11680	A2	Elliesen et al.	04-03-1997		
	B2	CA	2,188,907		Dittgen et al.	02-27-2001		

### OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	Prosecution History of Corresponding international Application No. PCT/IB00/01213 at EPO.	
	C2	Casper et al., "Estrogen and Interrupted Progestin: A New Concept for Menopausal Hormone Replacement Therapy," <i>American Journal of Obstet Gynecol</i> , Vol. 168, No. 4, pp. 1188-1196.	
	C3	Lignières, "Oral Micronized Progesterone," <i>Clinical Therapeutics</i> , Vol. 21, No. 1, 1999, pp. 41-60.*	
	C4	Nickisch et al., "Acid-Catalyzed Rearrangements of 15 $\beta$ ,16 $\beta$ -methylene-17 $\alpha$ -pregnene-21,17- $\alpha$ -carbolactone Derivatives," <i>Tetrahedron Letters</i> , Vol. 27, No. 45, 1986, pp. 5463-5466.	
	C5	Translation of Cite No. C4.	
	C6	Shah et al., "Preformulation Study of Etoposide: identification of Physicochemical Characteristics Responsible for the Low and Erratic Oral Bioavailability of Etoposide," <i>Pharmaceutical Research</i> , Vol. 6, May 1999, pp. 408-412.	
	C7	Montel et al., "Development of a New Tablet Formulation of Theophylline: In Vitro and In Vivo Studies," <i>Drug Development and Industrial Pharmacy</i> , Vol. 9, No. 3, 1983, pp. 399-420.	
	C8	Arias et al., "Dissolution Properties and In Vivo Behaviour of Triamterene in Solid Dispersions With Polyethylene Glycols," <i>Pharm-Acta-Helv</i> , Vol. 71, No. 4, 1996, pp. 229-235.	

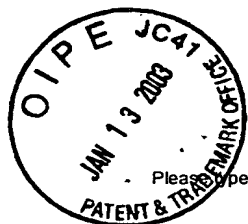
Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box →



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

2

of

2

### Complete if Known

Application Number	09/654,227
Filing Date	August 31, 2000
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1617
Examiner Name	M. Bahar
Attorney Docket Number	PLOVIN-1A

### OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C9	Berlin et al., "Phase I and Pharmacokinetic Study of a Micronized Formulation of Carboxyamidotriazole, A Calcium Signal Transduction Inhibitor: Toxicity, Bioavailability And The Effect Of Food," <i>Clinical Cancer Research</i> , January 2002, Vol. 8, No. 1, pp. 86-94	
	C10	Carlson et al., "Efficacy And Safety Of Reformulated, Micronized Glyburide Tablets In Patients With Non-Insulin-Dependent Diabetes Mellitus: A Multicenter, Double-Blind, Randomized Trial," <i>Clinical Therapeutics</i> , 1993, Vol. 15, No. 5, pp. 788-96.	
	C11	Duclos et al., "About A Pharmacokinetic Study Of Progesterone In Comelts," <i>Eur-J-Drug-Metab-Pharmacokinet</i> , Vol. 15, No. 2, Suppl., Abstr. 226, 1990.	
	C12	Fell et al., "Bioavailability Of Griseofulvin From A Novel Capsule Formulation," <i>The Journal Of Pharmacy And Pharmacology</i> , 1978, Vol. 30, No. 8, pp. 479-82.	
	C13	Hartmann et al., "Comparison Of Galenic Formulations Of Orlistate (Tetrahydrolipstatin). A Pharmacological Approach," <i>Drug Investigation</i> , 1993, Vol/Iss/Pg. 5/1 (44-50).	
	C14	Kohno et al., "Pharmacokinetics And Bioavailability Of Diltiazem (CRD-401) In Dog," <i>Arzneimittel-Forschung</i> , 1977, Vol. 27, No. 7, pp. 1424-8.	
	C15	Hsiao et al., "Method For Preparing An Oral Formulation Containing Acid-Sensitive Drugs," <i>Standard Chem. &amp; Pharm. Co., Ltd.</i>	
	C16	Klokkers et al., "Stabilization Of Acid Sensitive Benzimidazoles With Amino Acid/Cyclodextrin Combinations."	
	C17	Bruzzese et al., "Action Of Gastric And Intestinal Simulated Juice On Mepartricin Stability In Solid And Solubilized Form," <i>Il Farmaco-Ed. Pr.</i> , Vol. 32, No. 8, pp. 422-428.	
	C18	Anderson et al., "Pharmacokinetics And Bioavailability Of Omeprazole After Single And Repeated Oral Administration In Healthy Subjects," <i>Br. J. Clin. Pharmacol.</i> , 1990, Vol. 29, pp. 557-563.	
	C19	Bozdog et al., "Formulation And Stability Evaluation Of Enteric-Coated Omeprazole Formulations," <i>S.T.P. Pharma Sciences</i> , Vol. 9, No. 4, 1999, pp. 321-327.	

Examiner  
Signature

Date  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.